IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

CATHERINE ANTUNES

Plaintiff,

v.

UNIVERSITY OF VIRGINIA HEALTH SYSTEMS; XAVIER BECERRA, in his official capacity as Secretary of U.S. Department of Health and Human Services; and JANET WOODCOCK, in her official capacity as Acting Commissioner of the Food and Drug Administration

Defendants

COMPLAINT FOR DECLARATORY JUDGEMENT AND INJUNCTIVE RELIEF

Civil Action No. 3:21-cv-42

COMPLAINT

INTRODUCTION

1. Catherine Antunes is a nurse with six years of experience as a nurse and 13 years of experience in the healthcare field. She has been employed at University of Virginia Health ("UVA Health" or "UVA") since January of 2020, where she worked mandatory overtime during the height of the COVID-19 pandemic, and was exposed to the SARS-COV-2 virus on a daily basis. UVA Health management's most recent evaluation (6/30/2021) rated her work as "fully meets expectations" and described her as "an exceptional asset to the team," with "astute clinical skills" and "natural leadership ability."

2. Despite this dedication and performance, Catherine will be fired on Tuesday, November 9, not because she has failed in her ability to provide needed healthcare; and not because she presents a medical risk to her patients and co-workers. UVA Health will be firing her because she has declined to accept an unapproved vaccine that, according to the published literature available at the time of filing: 1) does not prevent transmission of the disease; 2) does not confer antibody immunity to the SARS-COV-2; 3) does not prevent vaccinated persons from getting the disease; 4) does not prevent the development of serious symptoms or hospitalization; and 5) has significant and potentially life-threatening short and long-term side effects.

3. In respectfully declining the COVID-19 vaccine, Ms. Antunes is simply asking for the treatment that UVA Health is required to afford to its patients as a matter ethics, policy, and law—the ability to accept or decline medicine within a framework of informed consent, which, by definition, excludes any coercive measures. By forcing Ms. Antunes to choose between an unapproved vaccine and her livelihood, UVA Health, exerting coercive pressure on a private healthcare decision. UVA Health is also unconstitutionally and illegally creating at least three (3) classes of persons among its work force: those who are vaccinated, those who are "fully vaccinated" and those who are unvaccinated.

Operating within a discriminatory framework that the U.S. Department of Health and Human Services enforces, UVA is not only abandoning its professed commitments to the bedrock principles of medical ethics, UVA Health is also violating applicable laws and the U.S. Constitution.

JURISDICTION AND VENUE

4. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331 and

1343(a)(3)-(4) (equitable relief), and 42 U.S.C. §§ 1983 and 1988, as well as under nonstatutory equitable jurisdiction. The claims here arise under the Constitution and statutes of the United States and because the Plaintiff seeks prospective redress against state actors in their official capacity to end the deprivation, under state law, of her rights, privileges, and immunities secured by federal law.

5. Venue for this action properly lies in this District pursuant to 28 U.S.C. § 1391 because the Plaintiff resides in this judicial district and a substantial part of the events, actions, or omissions giving rise to the claim occurred in this judicial district, where the University of Virginia is principally located.

6. This Court's equitable powers permit it to issue nonstatutory injunctions to protect the Plaintiff against state actors. *See Trump v. Vance*, 140 S. Ct. 2412, 2428-29 (2020) [citing *Ex parte Young*, 209 U.S. 123, 155–156 (1908) (holding that federal courts may enjoin state officials to conform their conduct to federal law)]. Defendants UVA Health possess the necessary connection to the establishment and enforcement of UVA Health's vaccine mandate. *See, e.g., Bostic v. Schaefer*, 760 F.3d 352, 371 n.3 (4th Cir. 2014) (Virginia's Registrar of Vital Records could be sued under *Ex parte Young* for unconstitutional actions related to marriage rights because he was charged with ensuring compliance with the Commonwealth's marriage laws).

7. This Court may also issue declaratory relief pursuant to 28 U.S.C. § 2201. Additionally, "[f]urther necessary or proper relief based on a declaratory judgment may [also] be granted ...," including via injunction. *See Powell v. McCormack*, 395 U.S. 486, 499 (1969) ("A declaratory judgment can then be used as a predicate to further relief, including an injunction. 28 U.S.C. § 2202 ....").

PARTIES

8. Plaintiff Catherine Antunes is a Registered Nurse (2015) with a B.S. in Science and Nursing from Shenandoah University (2014). As a temporary travel nurse, she gained experience working within seven different hospital systems, including John Hopkins Bayview Medical Center in Baltimore, Maryland, before she joined UVA Health. Prior to earning her certification as a Registered Nurse, she worked as a Certified Nurse Aide for a total of thirteen (13) years of healthcare experience total. She joined UVA Medical Center in Charlottesville in January of 2020. Since the beginning of the COVID-19 pandemic, she has worked two rounds of mandatory overtime during a time when the system added 40 beds but lost over 100 nurses.[1]

9. University of Virginia Health (UVA Health) is part of a public university, and is one of the most well-respected health systems in the nation,[2] including an academic medical center and health system featuring a cancer center, a children's hospital, three community hospitals, and a network of clinics throughout the Commonwealth of Virginia. In 2021, UVA Health employed 8,492 Full-Time Equivalents, including 4,257 professional nurses.

10. Xavier Becerra is the Secretary of Health and Human Services. The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services. As part of this mission, HHS oversees the drug approval process, including clinical trials.

11. Janet Woodcock is the acting Commissioner of the Food and Drug Administration (FDA), which is an HHS agency that regulates clinical investigations of products under its

1 UVAHealth.com, *Facts & Statistics*, at https://uvahealth.com/about/facts-stats (last visited November 5, 2021).
2 UVAHealth.com, citing U.S. NEWS AND WORLD REPORT, https://uvahealth.com (last visited November 5, 2021).

jurisdiction, such as drugs, biological products, and medical devices. The FDA has direct oversight of the drug approval process.

FACTUAL BACKGROUND

12. On December 11, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the pharmaceutical manufacturer Pfizer's vaccine, which it developed for the prevention of coronavirus disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)("COVID-19" or "COVID" herein). See Exhibit A.

13. On December 18, 2020, FDA issued an EUA for Moderna's vaccine for the prevention of COVID-19. See Exhibit B.

14. On February 27, 2021, FDA issued an EUA for Janssen (Johnson and Johnson)'s COVID-19 vaccine. On April 23, 2021, the FDA amended its EUA to warn of a "very rare and serious type of blood clot in people who receive the vaccine." See Exhibits C and D.

15. UVA Health hired Ms. Antunes in January of 2020. From the beginning of her tenure, in response to the COVID-19 pandemic, UVA Health began implementing measures to mitigate the spread of the disease among staff and to patients. This included mandatory Personal Protective Equipment (PPE), but also daily attestation that the employee was not experiencing any symptoms.

16. On July 7 of this year, UVA Health notified its employees via company-wide email co-signed by K. Craig Kent, MD, Chief Executive Officer of UVA Health; Bobby Chhabra, MD, President of University Physicians Group; Pam Cipriano, PhD, Dean of the School of Nursing; Wendy Horton, PharmD, MBA, Chief Executive Officer of the Medical Center; and David Wilkes, MD, Dean of the School of Medicine, that employees who were not vaccinated and

whose work required them to be physically present at UVA at any time would have to receive weekly testing beginning August 2 of this year. See Exhibit E.

17. On August 23, 2021, the Food and Drug Administration (FDA) approved Pfizer's COVID vaccine, "Comirnaty." In accompanying literature, FDA admittted that "Comirnaty" is "legally distinct" with "certain differences" from Pfizer's BioNTech vaccine that had received an EUA.[3]

18. On August 25 of this year, the same executives, via company-wide email, and citing "the increasing number of new COVID-19 cases in recent weeks" announced that "[W]e…will now require all team members without a religious or medical exemption to be vaccinated against COVID-19 by November 1, 2021." The same email went on to say, "Any team member not meeting the vaccination requirement deadline will be subject to disciplinary action up to and including to termination." See Exhibit F.

19. The BioNTech remains authorized only according the EUA process and has not received full approval from the FDA.

20. Upon information and belief, neither the FDA, Pfizer, nor any other entity, has publicly provided information that would permit either vaccine consumers or entities like UVA Health which seek to mandate its use, to understand what the "differences" between the two vaccines are or how those "differences" are or not relevant to the approval process or to a patient's informed consent.

21. Subsequent to Comirnaty's approval, Ms. Antunes began inquiring about the vaccines that UVA would be making available to its employees. On August 29 of this year, Ms. Antunes

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3 FDA.gov, Q&A for Comirnaty (COVID-19 Vaccine mRNA), https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna (last visited November 4, 2021).

began emailing the account UVA set up for questions regarding the COVID vaccine, "covidvax@hscmail.mcc.virginia.edu." In an exchange that went back-and-forth over the course of several days, the administrator of the account (the "Account Administrator," who only identified himself or herself as "EH") informed Ms. Antunes that UVA was not offering the vaccine that had received full FDA approval, "Comirnaty," to its employees because it was not available to UVA, and that UVA would make the Comirnaty available to them when they were able to acquire it. See Exhibit G.

22. Upon information and belief, UVA has not yet offered Comirnaty, which remains the only vaccine to receive full FDA approval, to its employees.

23. Upon information and belief, the vaccine that may properly be labeled "Comirnaty," is not yet available anywhere in the United States.

24. No other COVID vaccine that has received full approval from the FDA is available to the public. All of the vaccines that are currently available for the treatment of COVID-19, including Comirnaty, remain in clinical trials.[4]

25. UVA Health is not only a division of a state university, it is the recipient of numerous grants to administer both state and federal health programs, and is otherwise the recipient of a large amount of public funding and benefits, both federal and state.

26. Ms. Antunes has not, to date, received any of the vaccines currently available for the treatment of COVID-19 and currently has no plans to take any. She does not have a categorical objection to vaccines generally and is, for example, in the practice of receiving the influenza vaccine every year.

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4 Pfizerclinicaltrials.com, https://www.pfizerclinicaltrials.com/find-a-trial?search=Coronavirus,COVID-19&distance=1000&age=7 (last visited November 5, 2021).

27. UVA Health has granted health and religious exemptions that, upon information and belief, number in the dozens, even into the hundreds. Those with religious and / or medical exemptions continue to work at UVA Health.

COUNT ONE

Violation of provisions of the Food, Drug, and Cosmetic Act

28. The "required conditions" section of the statute under which the three vaccines Ms. Antunes is currently able to access have become available, 21 U.S. Code § 360bbb–3(e)(1)(A)(ii)(III), includes the condition that the HHS Secretary "ensure that individuals to whom the product is administered are informed…of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

29. The Department of Justice Office of General Counsel has opined that this statute speaks only to the information the Secretary provides, but does not have any binding effect on third parties attempting to punish people for refusing the product.

30. In one sense, Plaintiff agrees with DOJ's assessment: the statute does not bind third parties. The statute binds the Secretary, and to more than DOJ acknowledges. The statute binds the Secretary to inform the users of the option to refuse the product, but also to ensure that that option actually exists. To read it otherwise is to imply that Congress intended to require the HHS Secretary to affirm that an option exists when it does not. This would be an absurd result.

31. In the absence of such conditions, that is, where it is being forced on a person using economic or other coercion or force, it is necessary for the Secretary to deny distribution of the drug, or to take some other measures. The Secretary must deny access to the entities that would

abandon the bedrock principle of informed consent and would seek to engage in coercive behavior.

COUNT TWO
Violation of the U.S. Constitution
Unconstitutional condition

32. The Supreme Court has, over the years, struck down laws and policies that impose unconstitutional conditions on the expenditure of federal funds. *See, e.g., Federal Communications Commission v. League of Women Voters of California et al.* 468 U.S. 364 (1984).

33. Here, UVA imposes an unconstitutional condition on employment at a public university: that employees surrender their constitutional right to refuse unwanted medical treatment in order to be employed at a public university. The nature of this surrender is complete and irreversible: Plaintiff cannot be vaccinated at work and unvaccinated in her private life.

COUNT 3
Violation of the U.S. Constitution
Equal Protection

A. Strict scrutiny.

34. The Equal Protection Clause of the Fourteenth Amendment to the United States Constitution provides that "[n]o state shall deny to any person within its jurisdiction the equal protection of the laws."

35. In its analysis of whether a state has denied a person the equal protection of the laws, a Court will apply strict scrutiny, intermediate scrutiny, or rational basis scrutiny depending on whether the discrimination affects a suspect class of people. *See, Plyler v. Doe*, 457 U.S. 202, 215–21 (1982).

36. Whether a person is a member of a "suspect class" of people is an analysis that has developed over time into one that will ask certain questions, including whether that class is "subjected to" a "history of purposeful unequal treatment" or "relegated to" a position of "political powerlessness" such that it commands "extraordinary protection from the majoritarian process." *San Antonio Indep. Sch. Dist. v. Rodriguez*, 411 U.S. 1, 28 (1973).

37. The development of this analysis represents the efforts of the court over many years and over numerous changes in roster to articulate something that Justice Lewis F. Powell put in the following way:

> The fundamental character of our government is democratic. Our constitution assumes that majorities should rule and that the government should be able to govern. Therefore, for the most part, Congress, and the state legislatures, should be allowed to do as they choose. But there are certain groups that cannot participate effectively in the political process. And the political process therefore cannot be trusted to protect these groups in the way it protects most of us. Consistent with these premises, the theory continues, the Supreme Court has two special missions in our scheme of government: First to clear away impediments to participation, and to ensure that all groups can engage equally in the political process; and Second, to review with heightened scrutiny legislation inimical to discrete and insular minorities who are unable to protect themselves in the legislative process. Lewis F. Powell, Jr., *Carolene Products Revisited*, 82 COLUM. L. REV. 1087, 1089 (1982).

38. Ms. Antunes's ethnic heritage and Catholic religion may constitute a colorable argument for a "strict scrutiny" analysis if the unequal treatment was, in this case, drawn along those lines, but they are not.

39. And yet, the analyses above that Justice Powell has so helpfully distilled for us speak directly to the lines of distinction that HHS and UVA have drawn. They speak, however, in a negative sense, that is—not to who she is (a racial, ethnic, or religious minority, for example), but who she is *not*. UVA's discrimination deserves strict scrutiny because she is not part of a group that has been singled out for preferential treatment.

40. HHS and UVA come to their line-drawing exercise as part of a medical / pharmaceutical / regulatory framework that, in its aggregate, enjoys self-reinforcing privileges and advantages that are at work in this case and that are impossible to deny. The makers of the vaccines in this case enjoy immunity from liability both as entities whose products come to the public during the COVID-19 pandemic[5] and as makers of vaccines (42 U.S. Code § 300aa–22). They are, for better or for worse, able to amass gargantuan amounts of capital, some of it received in very large quantities from governments both domestic and foreign[6] for the development of these particular vaccines, vaccines which they in turn sell to the public in transactions which are themselves publicly subsidized, and which lead to billions of dollars in profit.[7] Drug makers deploy this capital in ongoing lobbying activities directed toward both major U.S. political parties, and which few industries are able to match.[8] All major forms of media have come to depend on their advertising revenue,[9] which is also of a nature that few industries are able to rival.

41. The agencies tasked with regulating or otherwise interacting with the pharmaceutical industries are often staffed with people who are former employees of

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5 *See,* PHE.gov, https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last visited November 5, 2021)("The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of the Department of Health and Human Services (Secretary) to issue a PREP Act declaration. The declaration provides immunity from liability (except for willful misconduct) for claims of loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions;[...] and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures.)

6 https://fortune.com/2020/11/09/pfizer-vaccine-funding-warp-speed-germany/

7 Jake Epstein, *Pfizer expects to make nearly as much revenue just from COVID-19 vaccines in 2021 as it earned in all of 2020*, BUSINESSINSIDER, (November 2, 2021) at https://www.businessinsider.com/pfizer-2021-vaccine-revenue-close-to-2020-total-earnings-2021-11 (last visited November 5, 2021).

8 Olivier J. Wouters, PhD, *Lobbying Expenditures and Campaign Contributions by the Pharmaceutical and Health Product Industry in the United States, 1999-2018*, JAMA Intern Med. 2020;180(5):688-697(2020) at https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2762509 (last visited November 5, 2021).

9 Beth Snyder Bulik, *The top 10 ad spenders in Big Pharma for 2020*, FIERCEPHARMA, (April 19, 2021), at https://www.fiercepharma.com/special-report/top-10-ad-spenders-big-pharma-for-2020 ("Total pharma advertising spending topped $6.58 billion in 2020, according to Kantar measured media. That's just a notch above the 2019 total of $6.56 billion, but still noteworthy in a year that saw U.S. advertising spend drop by 13% overall.")

pharmaceutical companies or are on their way there. To take the Trump Administration as just one example:

- FDA Commissioner Scott Gottlieb advised the pharmaceutical industry before becoming commissioner and became a member of Pfizer's Board of Directors after his tenure.
- His successor, Stephen Hahn, left for Flagship Pioneering Co., a venture capital firm that focuses on life sciences and holds a 6.1% stake in Moderna.
- The Secretary of Health and Human Services (HHS), Alex Azar II, worked for Eli Lilly before becoming the HHS Secretary.
- Joe Grogan, Chief of the White House Domestic Policy Council, was a government affairs executive for pharmaceutical manufacturer Gilead Sciences, Inc. before taking a job with the Administration.

42. This phenomenon is not limited to the Trump Administration, or the executive branch—61.34% of lobbyists for the pharmaceutical industry are former government employees.[10]

43. The Plaintiff does not raise these facts to judge them. Certainly, there are checks and balances in place, and these phenomena have their justifications.

44. The Plaintiff raises these phenomena, however, to make the case that the line-drawing exercise between those who receive greater protection than others in this context merits strict scrutiny because drug manufacturers, who have a large financial stake in the public policy regarding vaccines, are able to influence the decision-making process about the regulatory framework governing drug approval, the trends and official opinions about the standard of care,

10 OpenSecrets.org, Industry Profile: Pharmaceuticals / Health Products, https://www.opensecrets.org/federal-lobbying/industries/summary?cycle=2020&id=H04 (last visited November 5, 2021).

and the regulatory framework that surrounds the administration of these vaccines, in ways that a single nurse, or anyone among the class of typical consumers of the product, simply do not.

45. Perhaps this is all for the good. On the other hand, an objective observer in fairness must acknowledge that an unscrupulous pharmaceutical company who wanted to rush a product to market, minimize concerns about its safety, have the medical community adopt it as the standard of care, and have governments mandate its use, would have plenty of tools to do so in the framework described above, and could position itself well to at least try. This is by design. By contrast, a working-class nurse who had concerns about the safety of a vaccine, even concerns that she has personally witnessed play out in a clinical setting, and that turn out after investigation to be entirely meritorious, would have far fewer tools at her disposal in the same framework.

46. As a factual matter, the pharmaceutical industry is at once the industry with the most at stake financially from our nation's vaccine policy, and with the most power to influence that policy one way or another. We can say with certainty that the industry is powerful enough to influence policy. Perhaps it is not too much to ask the Court to agree that the industry is powerful enough to *distort* policy. Fortunately, the framework that has privileged the pharmaceutical industry also equips it with more than enough resources to withstand the rigors of strict scrutiny in this case.

47. Furthermore, it bears mention that the politicians who oversee the various regulatory processes in play here are under intense political pressure to 1) mobilize the resources of the government to keep COVID numbers down and 2) minimize legitimate risks associated with the means of doing so. It is not necessary to believe that a politician would ever do such a thing, but we believe it to be prudent to acknowledge that it is a risk and as a neutral arbiter, apply strict

scrutiny to mitigate against this risk.

48. Finally, the nation, and much of the world, finds itself in the throes of a sustained effort to *create* such a "discrete and insular" class of unvaccinated individuals, who cannot eat in some restaurants, attend certain concerts and gatherings, and who are being fired from their jobs and denied employment opportunities.

49. The dynamics in play, as described above, merit a strict scrutiny analysis.

B. Analysis

50. The Equal Protection Clause directs that all persons similarly circumstanced shall be treated alike. *See, Plyler v. Doe Texas v. Certain Named and Unnamed Undocumented Alien Children*, 457 U.S. 202, 216 (1982)(citations omitted). Where they are not, courts will require an explanation of the government instituting the unequal treatment, and in a case where the unequal treatment disadvantages a member of a suspect class, that justification must withstand strict judicial scrutiny, meaning that the government must show that a course of action is "narrowly tailored" to serve a "compelling government interest." *Id* at 217.

51. When UVA decided to require its employees to receive a COVID-19 vaccine as a condition of employment, it was able to do so because HHS has set up a discriminatory framework for the administration of the vaccines.

21 CFR Part 50 applies to:

> [A]ll clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic

products.

52. The regulation goes on to state that, except in situations where conditions make informed consent impossible (where, for example, there is an immediate danger and a medical condition makes consent impossible):

> [N]o investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

53. Key to this regulatory passage are the concepts of "coercion" and "undue influence." Threatening a person's job or livelihood to obtain his or her consent to be a part of a clinical trial would be a form of coercion that these regulations render impermissible. Indeed, the Belmont Report,[11] which HHS created and which remains a touchstone for the treatment of human subjects during clinical trials, states:

> Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance...Unjustifiable pressures usually occur when persons of authority or commanding influence--especially where possible sanctions are involved-- urge a course of action for a subject. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

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11 *See*, HHS.gov, The Belmont Report, at https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html. ("The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles. Informed by monthly discussions that spanned nearly four years and an intensive four days of deliberation in 1976, the Commission published the Belmont Report, which identifies basic ethical principles and guidelines that address ethical issues arising from the conduct of research with human subjects.")

> Unjustifiable pressures usually occur when persons in positions of authority or commanding influence -- especially where possible sanctions are involved -- urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.[12]

54. According to this regulatory framework, if UVA, while administering a clinical trial on behalf of a pharmaceutical company, ordered its employees to participate or lose their jobs, such a policy would be a clear instance of coercive influence that would constitute a violation of the relevant regulations and would be impermissible.

55. Although the FDA issued its Emergency Use Authorization alongside clinical trials that remain ongoing, it acknowledges no such protections against coercion in its administration of 21 U.S.C. § 360bbb-3, the statue that created the EUA, despite subsection (e)(1)(A)(ii)(III), which requires "appropriate conditions designed to ensure that individuals to whom the product is administered are informed of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

56. In the context of the vaccines in question, HHS and the FDA have, unwittingly or not, created two similarly situated classes of people, one with more protections against coercion than the other.

57. In this instance, FDA would have to have a public justification showing that imparting greater protections to trial participants than to those receiving the vaccine as under an EUA is a policy that is narrowly tailored and serves a compelling government interest.

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12 *Id.*

58. HHS and the FDA offer no public justification, and it is difficult to imagine that there could be any justification, for treating these two similarly situated populations of people differently. This distinction is not narrowly tailored, it is not tailored. The drugs are the same, but because of the FDA's inadequate regulatory structure, some will accept the vaccine in an environment where they will—by law—be free of coercion over whether they exercise their decision. Others, when considering whether they will take the vaccines, will be subject to the loss of their entire livelihoods.

59. The lack of any conceivable justification for this disparate treatment of similarly situated recipients of the vaccine compels the conclusion that there can be no narrowly tailored, compelling government interest that would justify it, that HHS has violated the Equal Protection Clause of the 14th Amendment, and that UVA's vaccine mandate cannot stand.

COUNT FOUR
Violation of the U.S. Constitution
Fourth Amendment prohibition against unreasonable searches and seizures

60. The Supreme Court in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990) recognized that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions." *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261, (1990). Without much elaboration, the Court understandably rooted this principle in the Due Process clause of the Fourteenth Amendment.

61. While the Plaintiff does not take issue with the idea that the Constitution stands for the principle that individuals may refuse unwanted medical treatment, the Plaintiff does suggest that this principle is found concurrently, or more properly, in the Fourth Amendment, which

provides that, "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated [...]" Here, the state, through UVA Health, is using economic coercion to commandeer Ms. Antunes's immune system for its own purposes.

62. While analysis of the Fourth Amendment is almost (or entirely) found in the context of criminal law, when considered alongside the Fourteenth Amendment, it has the benefit of being expressly written in the U.S. Constitution, rather than implied in its interpretation. Its history of consideration in the criminal context, in other words, should be no bar to its consideration in the civil context, especially in light of the fact that Courts, including the Supreme Court, have given the consideration to the principle as an element of the Fourteenth Amendment, despite its absence in the actual language of the Amendment.

63. Whether this principle sounds in the Fourth Amendment, the Fourteenth Amendment, or both, this principle is one that makes UVA's conduct in this episode unlawful. Courts have, since the 1970s, treated economic coercion and harassment for the purpose of obtaining sexual favors as unlawful sex discrimination under Title VII of the Civil Rights Act. The problem in sexual harassment cases tends to be the coercion which is of an economic nature and which induces the harassed to do what he or she would not do but for the harassment / coercion. Men (or women) are using economic power to secure sexual access to women they otherwise would not have.[13]

64. UVA's mandate suffers from the same problem—it is using economic power to secure access to a constitutionally protected space—an individual's "person," and specifically here, the precious and inviolable inner workings of that "person."

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13 CATHARINE MACKINNON AND RIVA SIGEL, DIRECTIONS IN SEXUAL HARASSMENT LAW 22 (2012)

65. There is no place for this in our Constitutional system, and fundamentally, this marks the end of the analysis. Yet, the Fourth Amendment asks whether a seizure is reasonable, and "determining that a person has a 'liberty interest' under the Due Process Clause does not end the inquiry; "whether respondent's constitutional rights have been violated must be determined by balancing his liberty interests against the relevant state interests." *Cruzan*, at 279.

66. The countervailing interest is certain to be UVA's ability to mitigate the risks of Employees and patients catching an infectious disease during a pandemic.

67. Fortunately, our Courts know better. "[E]ven in a pandemic, the Constitution cannot be put away and forgotten." *Roman Catholic Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 68 (2020). UVA Health, for its part, hardly even attempted to offer a justification for its actions, citing only the "increasing number of new COVID-19 cases in recent weeks (particularly the highly transmissible delta variant)," and that they wanted to keep its environment "safe and healthy as possible." It provided no context for the numbers it mentioned; it did not even provide the numbers, or how it came to attribute any of the new numbers to the "highly transmissible delta variant."

68. We know from the science that:

- People who have had the vaccine can still become sick with COVID-19.[14]
- People who have had the vaccine can still spread the disease.[15]
- People who have had the vaccine can still spread the disease to other people who have

14 Prerak, et. al., *Hospitalisation among vaccine breakthrough COVID-19 infections*, THE LANCET, (September 7, 2021), at https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00558-2/fulltext.
15 Brown, et. al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021*, CENTER FOR DISEASE CONTROL AND PREVENTION MORBIDITY AND MORTALITY WEEKLY REPORT, (August 6, 2021), at https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm?s_cid=mm7031e2_w.

had the vaccine.[16]

- Personal Protective Equipment (PPE) prevents the spread of COVID-19[17]

69. The COVID-19 vaccines available to the public offer the benefit of preventing the severest symptoms in the people who have received the vaccine. They do not, however, prevent the spread of the disease. If, by "safe and healthy as possible" UVA Health means the lowest COVID-19 infection rate possible, none of the vaccinations currently available can serve as a means to achieve this goal. UVA Health offers no rational basis for this policy, and there is none available.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and all others similarly situated, respectfully pray for relief as follows:

A. Hold unlawful and set aside UVA's vaccine mandate

B. Hold unlawful and set aside Secretary Becerra and Acting Commissioner Woodcock's unequal treatment of similarly situated classes of vaccine recipients

C. Issue declaratory relief declaring the Defendants' actions unlawful

D. Issue preliminary and permanent injunctive relief enjoining Defendants UVA Health and their agents from requiring the COVID-19 vaccine as a condition of employment. See attached Motion for Temporary Restraining Order and Preliminary Injunction.

E. Award Plaintiff costs and reasonable attorneys' fees.

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16 *Id.*

17 Sohil R. Sud, MD, MA, COVID-19 and Keeping Clean: A Narrative Review To Ascertain the Efficacy of Personal Protective Equipment To Safeguard Health Care Workers Against SARS-CoV-2, 10 Hosp. Pediatrics 570, 573 (July 2020), at https://hosppeds.aappublications.org/content/hosppeds/10/7/570.full.pdf (last visited November 5, 2021).

F. Award such other and further relief as the Court deems equitable and just under the circumstances.

Dated: November 5, 2021

Respectfully Submitted,

Counsel

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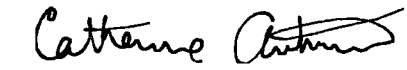
CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 7, 2021, that I have cause the foregoing documents to be served upon Defendants.

SCOTT LLOYD

VERIFICATION

Pursuant to 28 U.S.C. § 1746, I, CATHERINE ANTUNES, declare under penalty of perjury that the foregoing is true and correct. Executed on November 7, 2021.



CATHERINE ANTUNES